

901 E. 233rd Street Carson, California 90745-6204 310/835-8400 Fax 310/835-6615

May 27, 1997

Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 "C" Street S.W. Washington, DC 20204



0159 '97 SEP 19 P1:45

Section 403(r)(6) Notification

Dear Sir or Madam:

In response to the courtesy letter received on November 19, 1996 from the FDA, suggesting that our previous statement for this product was a drug claim, LEINER HEALTH PRODUCTS notifies FDA that it is resubmitting the following restructured statement in accordance with the requirements of section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act:

Immune System

Animal and laboratory studies show that echinacea stimulates the body's own defenses.

on the following product:

Your Life® Echinacea

Very truly yours,

LEINER HEALTH PRODUCTS

Gale Bensussen, President

cc: Michael Bradley, Director of Regulatory Affairs

William Cochran, Regulatory Affairs